DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 8, 2014

Elekta Ltd.
% Mr. George Papagiannis
Regulatory Affairs
2050 de Bleury, Suite 200
Montreal, Quebec, H3A 2J5
CANADA

Re: K141855
Trade/Device Name: Clarity®
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE, IWB, KPQ
Dated: July 10, 2014
Received: July 11, 2014

Dear Mr. Papagiannis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141855

Device Name

Clarity®

Indications for Use *(Describe)*

Clarity® is indicated for use in external beam radiation therapy. It provides 3D ultrasound and hybrid imaging of soft tissue anatomy to aid in radiation therapy simulation and planning, and to guide patient positioning prior to the delivery of treatment (Image Guided Radiation Therapy).

When configured with an autoscan probe kit for transperineal ultrasound (TPUS) imaging, Clarity® may be used to continuously track and monitor the motion of the prostate and to accurately and precisely guide patient positioning during the delivery of treatment (Intrafractional Position Tracking and Monitoring).

When configured with a gating option, Clarity® may also interface with radiation delivery systems equipped with a compatible external gating control device. With this option, while in tracking and monitoring mode, Clarity® can signal the radiation delivery system to automatically impose a beam-hold when the position of the tracked anatomy has exceeded pre-defined monitoring (tracking) limits, and signal again to release the beam-hold when the tracked anatomy returns to a position within those limits (Exception Gating). Exception gating has been shown to be compatible with radiation delivery systems equipped with Elekta's Response™ Gating Control System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

ELEKTA

510(k) Summary

K141855

October 07, 2014

Trade/Device Name:	**Clarity®**
Common Name (GMDN):	Patient positioning system, ultrasound
Regulation/Classification:	Medical charged-particle radiation therapy system (21 CFR 892.5050, Product Code IYE) Radionuclide radiation therapy system (21 CFR 892.5750, Product Code IWB) Radiation therapy simulation system (21 CFR 892.5840, Product Code KPQ)
Regulatory Class:	Class II
Review Panel:	Radiology
Submitter/Manufacturer:	Elekta Ltd.
Establishment Registration No:	3004747535
Address:	2050 Bleury, Suite 200 Montreal, Quebec H3A 2J5, Canada Tel: (+1) 514-840-9600 Fax: (+1) 514-840-9666
Contact:	Tony Falco, PhD

Introduction

This 510(k) Summary has been prepared in accordance with 21 CFR 807.92. It summarizes device safety and effectiveness information to provide an understanding of the basis for a determination of substantial equivalence.

Predicate Device Information

Clarity® (K121663, Dec 05, 2012; Product Codes: IYE, IWB, KPQ)

Intended Use / Indications for Use

Clarity® is indicated for use in external beam radiation therapy. It provides 3D ultrasound and hybrid imaging of soft tissue anatomy to aid in radiation therapy simulation and planning, and to guide patient positioning prior to the delivery of treatment (Image Guided Radiation Therapy).

When configured with an autoscan probe kit for transperineal ultrasound (TPUS) imaging, *Clarity*® may be used to continuously track and monitor the motion of the prostate and to accurately and precisely guide patient positioning during the delivery of treatment (Intrafractional Position Tracking and Monitoring).

When configured with a gating option, *Clarity*® may also interface with radiation delivery systems equipped with a compatible external gating control device. With this option, while in tracking and monitoring mode, *Clarity*® can signal the radiation delivery system to automatically impose a beam-hold when the position of the tracked anatomy has exceeded pre-defined monitoring (tracking) limits, and signal again to release the beam-hold when the tracked anatomy returns to a position within those limits (Exception Gating). Exception gating has been shown to be compatible with radiation delivery systems equipped with Elekta's *Response™ Gating Control System.*

Device Description

The *Clarity*® system integrates medical diagnostic ultrasound, real-time optical position tracking and proprietary software to acquire and reconstruct 3D images of soft-tissue anatomy for use in external beam radiation therapy. *Clarity*® offers a non-invasive, non-ionizing means for accurate and precise localization of anatomical structures and patient positioning relative to the treatment isocenter.

The *Clarity*® system (Model 310C00) is configured around a mobile image acquisition station with an integrated ultrasound scanner, high-resolution touch screen, and high-performance computer system running the *Clarity*® software. It may be used at the patient's side in the CT-Sim room (*Clarity*® *Sim*) and the treatment room (*Clarity*® *Guide*) when equipped with a ceiling-mounted optical tracking system, patient/couch position tracking tools and, optionally, remote control and treatment monitoring equipment. With the gating option, the *Clarity*® *Guide* acquisition station may interface with radiation delivery systems equipped with a compatible external gating control device.

Each acquisition station is configured with up to three optically-tracked ultrasound probes: one or two hand-held probes for manual scanning and a motorized (autoscan) probe for automated scanning. The user can select the probe and scanning method that is most appropriate for the target anatomy and the patient's clinical presentation. The autoscan probe remains in contact with the patient for continuous imaging of the prostate and surrounding anatomy using specifically designed positioning apparatus for transperineal ultrasound (TPUS); it is operated from the acquisition station's remote control and monitoring equipment interface (touch-screen identical to that on the mobile acquisition station).

A multimodality imaging phantom is used to calibrate *Clarity*® to the room coordinate system and to verify system integrity for sub-millimeter target localization accuracy and precision within each room (daily and monthly QC).

A dedicated high-performance server and workstation computer system running the *Clarity*® software is connected to *Clarity*® acquisition stations through the hospital's local area network. The server houses the central database and web server, and provides for interoperability with other imaging and treatment planning/simulation systems via the DICOM 3/RT protocol. The workstation is used for multimodality image fusion and review, soft-tissue structure definition, approval of patient positioning references, setup of monitoring parameters, and review of treatment and QC data. Optionally, additional *Clarity*® workstations may be connected to the central *Clarity*® server.

The *Clarity*® software is designed to step the user through a radiation therapy workflow or "course" and QC procedures. Different courses are defined to help classify patients in the database and to present the user with reminders, default choices and configuration settings tailored to the target anatomy (*e.g.*, prostate, bladder, liver, uterus & cervix, breast, head & neck). Such configurations include probe type, imaging (scan) presets, contouring and assisted segmentation tools, alert values for target misalignment, and prostate monitoring (tracking) parameters.

The typical use of the system for a radiation therapy course begins with the acquisition of a baseline 3D ultrasound (3DUS) scan with the patient in the planning position. The planning CT is imported, registered and fused with the 3DUS on the *Clarity*® workstation to verify the alignment of the target anatomy. The structures of interest are then defined and a baseline positioning reference including, if applicable, monitoring (prostate tracking) parameters are approved. Optionally, the 3DUS and related contours may be exported via DICOM to a third-party virtual simulator or treatment planning system.

To assist with patient positioning prior to each treatment session, a new 3DUS scan is acquired and used to determine target displacement relative to the baseline planning-day position. Optical tracking of couch position allows for accurate and precise patient repositioning relative to the treatment isocenter (Image Guided Radiation Therapy).

Automatic image analysis identifies a soft-tissue structure such as the prostate in successive transperineal 3DUS images, which are acquired continuously during treatment, and allows *Clarity*® to track its motion and assist with patient repositioning (Intrafractional Position Tracking and Monitoring). When configured with the gating option, while in tracking and monitoring mode, *Clarity*® can signal the radiation delivery system to automatically impose a beam-hold when the tracked structure position has exceeded pre-defined monitoring (tracking) limits, and signal again to release the beam-hold when the structure returns to a position within those limits (Exception Gating).

Clarity® may optionally be configured to send calculated couch shifts for patient repositioning to the operator at the couch control user interface using the *MOSAIQ® Workflow Manager.*

A web-based interface is available for remote review and approval of positioning references and other treatment parameters, and review of completed treatment session and QC procedure data.

Comparison with Predicate Device

The current release of *Clarity*®, which includes usability improvements and expanded indications for exception gating, is substantially equivalent to the predicate device. The differences in labeling and technological characteristics do not raise new questions of safety and effectiveness for the intended use. A side-by-side comparison of key device characteristics is presented in the following tables:

Device Characteristic	Predicate Device (K121663)	Current Device
Equipment		
Medical imaging modality (acquisition station)	Mobile console with integrated diagnostic ultrasound scanner; Broadband curved (convex), linear, and autoscan probes	No Significant Change (Upgraded computer system specifications and improved mobile console aesthetics)
Optical tracking system	Passive infrared position sensor powered from acquisition station	No Significant Change (Independent power supply)
Patient/couch localization	Rigid tools fitted with infrared light reflecting markers	No Significant Change
System calibration and Quality Control	Proprietary multimodality phantom	No Significant Change
Remote control interface	Touch-screen duplicating main console via KVM device for image acquisition with autoscan probe	No Significant Change (Upgraded KVM device specifications for gating option)
Basic safety and essential performance standards	IEC 60601-1:2005 IEC 60601-2-37:2007 (Ultrasound) IEC 60601-1-2:2007 (EMC) IEC 60601-1-6:2010 (Usability)	AAMI/ANSI ES60601-1:2012 IEC 60601-2-37:2007 IEC 60601-1-2:2007 IEC 60601-1-6:2010

Device Characteristic	Predicate Device (K121663)	Current Device
Software / Functionality		
System calibration to room coordinate system and Quality Control	Manual characterization of phantom from high-resolution CT scan; Software-assisted calibration of optical sensor tilt detector, room's coordinate system and probe; Software-assisted daily QC process; Software-configurable mobile acquisition station for CT/Tx room	No Significant Change (Simplified system calibration and daily QC process; auto-configuration of mobile acquisition station based on optical tracking system ID)
Ultrasound image acquisition for daily target localization	Ultrasound imaging (scan) presets; Image adjustment controls; Display of previous scans for consistent image acquisition; Assisted soft-tissue segmentation; 3DUS-to-3DUS comparison	No Significant Change (Added "Live Guidance" for consistent probe positioning in daily prostate scans)
Couch localization and control interface	Option to send couch shifts for patient repositioning to MOSAIQ®	No Significant Change
Intrafractional prostate motion management	Tracking & monitoring with autoscan probe kit for transperineal ultrasound	No Significant Change (Improved user interface and tracking indicators)
Exception gating during prostate monitoring	No	Optional with compatible radiation delivery systems
Workstation & Server functionality	System-wide database; Automated multimodality image registration and fusion; workspaces for contouring and positioning reference definition; DICOM RT import/export, including beam & MLC data; positioning and monitoring parameters definition	No Significant Change (Compatible with Windows 7)
Web-based interface	Remote review of patient data and positioning reference approval	No Significant Change (Improved monitoring reports and added review of QA/QC data)

Summary of Clinical & Non-Clinical Testing

Clarity® has been developed and tested in compliance with regulatory guidance and recognized consensus safety standards. Software and system verification testing was conducted under typical and reasonably foreseeable use error and boundary conditions. Localization accuracy and precision specifications were verified with multimodality phantoms. Exception gating was validated with Elekta's *Response*™ *Gating Control System* under simulated treatment conditions. Formative evaluations and simulated use of the modified device with representative end-users were conducted in accordance with FDA guidance on human factors and usability engineering to assure the safe and effective performance of critical tasks. The test results from verification and validation activities demonstrate that *Clarity*® fulfills its design and risk management requirements, and is as safe and effective for its intended use as the predicate device.